K002384

DEC 15 2000

PREMARKET NOTIFICATION [510(k)] SUMMARY

Date: December 11, 2000

1. Submitter:
   International Business Strategies
   1667A Marsh Harbor Lane
   Mount Pleasant, SC 29464

2. Contact Person:
   William H. Roettger
   President

3. Contact:
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4. Proprietary Device Name:
   M-01 Oxygen Sensor
   M-02 Oxygen Sensor
   M-03 Oxygen Sensor
   M-04 Oxygen Sensor
   M-05 Oxygen Sensor
   M-06 Oxygen Sensor
   M-07 Oxygen Sensor
   M-10 Oxygen Sensor
   M-13 Oxygen Sensor
   M-25 Oxygen Sensor

5. Classification Name:
   Oxygen Analyzer (868-1720)

6. Common Name:
   Oxygen Sensor

7. Manufacturer:
   IT Dr. Gambert GmbH
   Hinter dem Chor 21
   23966 Wismar
   Germany

8. Contact Person:
   Rainer Boettcher
   Business Development Manager

9. Contact:
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10. Predicate Devices:
    K972992 Ceramatec (Maxtec) Oxygen Sensors

11. Indications for Use:
    IT Dr. Gambert's electrochemical oxygen sensors for medical applications are intended to be used as replacement sensors for certain oxygen analyzers intended to measure and display the concentration of oxygen in breathing gas mixtures.

12. Method of Operation:
    IT Dr. Gambert oxygen sensors measure the gaseous partial pressure of oxygen and consist of a lead anode and a cathode made of precious metal which are electrochemically linked by an electrolyte. A synthetic, oxygen permeable, membrane separates the environment from the cathode and the electrolyte (Clark principle). The oxygen diffusing through the membrane is reduced on the surface of the cathode and, then, polarized by the electrochemical potential of the anode. This reduction process produces an electrical current which is directly proportional to the partial pressure of oxygen in the environment. The electrochemical reaction at the surface of the cathode is complex. Simplified, the process can be expressed by the following chemical equation:

    $$O_2 + 2\,H_2O + 4\,e^- \rightarrow 4\,OH^-$$

    Corresponding to the reduction of oxygen at the cathode, the anode material is oxidized:

    $$2\,Pb \rightarrow 2\,Pb^{2+} + 4\,e^-$$

    When the cathode and the anode are electrically connected to a wire, the reduction process takes place and an ionic current flows through the sensor. The corresponding electrical current can be measured with a resistor connected in series. The electrochemical reaction, as well as the diffusion of the oxygen through the membrane, are temperature dependent. To compensate for the temperature dependency of the signal, the sensor current is fed over a matched

thermistor network. The temperature compensation network may reside in the sensor, or be incorporated in an attached analyzer.

The IT Dr. Gambert family of oxygen sensors and the predicate device oxygen sensors operate on the same principle described above and are exactly equivalent.

13. Description:

IT Dr. Gambert produces the following sensor configurations: M-01, M-02, M-03, M-04, M-05, M-06, M-07, M-10, M-13 and M-25. The design and operational characteristics of all IT Dr. Gambert oxygen sensors are identical. The different configurations are constructed to fit a variety of commercially available oxygen analyzers. IT Dr. Gambert oxygen sensors are electro-chemical devices which produce an electrical current directly proportional to the amount of oxygen contained in a breathing gas mixture. They are exactly equivalent to the listed predicate devices (also manufactured by IT Dr. Gambert GmbH) and substantially equivalent to all other electro-chemical oxygen sensors currently being marketed in the United States.

14. Conformity to a Recognized Standard:

IT Dr. Gambert oxygen sensors are classified as Class IIa devices according to EC-Council Directive 93/42/EEC Annex IX, Rule 2 and meet all of the provisions of ISO7767:1997. All IT Dr. Gambert sensors display CE Mark 0124.

15. Performance Comparison (constant Temperature, Pressure):

Product	Ceramatec (Maxtec)	M-01 M-02	M-03	M-04	M-07 M-10	M-05 M-06	M-13 M-25
Range	same	same	same	same	Same	same	same
Resp. time t_{90}	same	< 12 s	< 12 s	< 12 s	< 12 s	< 12 s	< 15 s
Temperature Range	5°C to 40°C	5° to 40°C	5° to 40°C	5° to 40°C	5° to 40°C	5° to 40°C	5° to 40°C
Humidity	same	same	same	same	same	same	same
Interference	same	same	same	same	same	same	same
Linearity	same	same	same	same	same	same	same
Operating Life	> 12 Mon.	> 12 Mon.	> 12 Mon.	> 12 Mon.	> 12 Mon.	> 12 Mon.	12 Mon.

Sensors in one column differ only in body shape and electrical connection, but are otherwise identical. Therefore they will be treated as one.

16. Conclusion:

IT Dr. Gambert oxygen sensors are exactly equivalent to all predicate oxygen sensors (also manufactured by IT Dr. Gambert GmbH) in terms of materials, performance and construction and operate on identical electro-chemical principles. They have been tested and comply with all provisions of ISO7767:1997, and have been found to be safe and effective when used in conjunction with manufacturer's recommendations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Mr. William H. Roettger
International Business Strategies
1667A Marsh Harbor Lane
Mount Pleasant, SC 29464

Re: K002384
M-01 through M-07, M-10, M-13, and M-25 Oxygen Sensors
Regulatory Class: II (two)
Product Code: 73 CCL
Dated: November 9, 2000
Received: November 14, 2000

Dear Mr. Roettger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K002384

Device Name: Oxygen Sensor

Indications for Use

The device is intended to be used as replacement sensors for certain oxygen analyzers intended to measure and display the concentration of oxygen in breathing gas mixtures.

Revised "Indications for Use" statement, 9/22/2000

PRESCRIPTION USE ✓ -OR- OVER-THE-COUNTER USE ____

Division of Cardiovascular & Respiratory Devices
510(k) Number K002384